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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GIBBS, TERRA C	
ART UNIT	**PAPER NUMBER**
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/980,265	BACHY ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006 and 13 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 20-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 9-14, 20-27, 29-34, and 36-42* is/are rejected.

7)☒ Claim(s) *8,28,35 and 43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Response to the 37 CFR 1.105 Request, filed April 7, 2006 and Applicant's Amendment and Remarks filed December 13, 2005.

Claims 1-14, 20, and 21 have been amended. Claim 19 has been canceled. New claims 22-43 are acknowledged.

Claims 1-14 and 20-43 are pending in the instant application.

Claims 1-14 and 20-43 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

Applicants Response to the 37 CFR 1.105 Request is acknowledged. Figures 1-11 referred to in the instant specification have been considered on the merits. It is noted that this response was submitted on April 7, 2006.

Priority

It is noted that in the previous Office Action mailed July 13, 2005, the instant claims were given priority to the filing date of the instant application, which is March 22, 2002, because support could not be found for the limitation "in which N_1 and N_2 are not both thymines". It is noted that in Applicant's Amendment filed December 13, 2005,

Applicant's have amended the claims and the phrase, "in which N_1 and N_2 are not both thymines" has been deleted.

It is noted that the instant application is a 371 of PCT/FROO/01566. PCT/FROO/01566 claims benefit of foreign application 99/07457, filed June 8, 1999. However the instant claims have not been afforded priority back to June 8, 1999 because support cannot be found for the specific nucleotide sequence: 5'-TTCATTC, as recited in claims 1, 21, and 36. Specifically, the instant claims have been amended and are drawn to a composition comprising an antigen and an immunostimulant oligonucleotide, the oligonucleotide comprising at least one nucleotide sequence having the formula, 5'-TTN$_1$N$_2$TT-3', wherein T signifies thymine, and N_1 and N_2 are each independently adenine, thymine, cytosine or guanine, and the nucleotide sequence is selected from the group consisting of:

5'-TTAATT-3; 5'-TTACTT-3; 5'-TTATTT-3; 5'-TTAGTT-3; 5'-TTTATT-3; 5'-TTTCTT-3 5'-TTTGTT-3; 5'-TTCCTT-3; **5'-TTCATTC**; 5'-TTCTTT-3; 5 '-TTGGTT-3; 5'-TTGATT-3; 5'-TTGTTT-3; and 5'-TTGCTT-3 and wherein the oligonucleotide lacks a dinucleotide CG in which the cytosine C is not methylated, and methods of using said composition. The Examiner cannot find support for the specific nucleotide sequence 5'-TTCATTC (shown above in bold) in foreign application 99/07457, filed June 8, 1999.

In summary, since foreign application 99/07457 does not support the specific nucleotide sequence 5'-TTCATTC, the instant application has been given priority to the filing date of the instant application, which is March 22, 2002.

If Applicants believe that they are entitled to an earlier priority date, the Examiner

urges Applicant to specifically point where support can be found for the specific nucleotide sequence 5'-TTCATTC in any other applications Applicants claim priority to.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed July 13, 2005, claims 1-3 were rejected under 35 U.S.C. 102(b) as being anticipated by Lang et al. (European Journal of Immunology, 1999 Vol. 29:3496-3506). **This rejection is withdrawn** in view of Applicant's Amendment filed December 13, 2005. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to the claims to recite, "A composition comprising an antigen and an immunostimulant oligonucleotide". It is noted that Lang et al. teach an immunostimulant oligonucleotide in the form of an antisense oligonucleotide, but do not teach wherein the oligonucleotide comprises an antigen.

In the previous Office Action mailed July 13, 2005, claims 1-5 and 9-14 were rejected under 35 U.S.C. 102(b) as being anticipated by Sanchez-Pescador et al. [U.S. Patent No. 5,618,674]. **This rejection is withdrawn** in view of Applicant's Amendment filed December 13, 2005. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to the claims to recite, "A composition comprising an antigen and an immunostimulant oligonucleotide". It is noted that Sanchez-Pescador et al. teach an immunostimulant oligonucleotide in the form of a probe, but do not teach wherein the oligonucleotide comprises an antigen.

In the previous Office Action mailed July 13, 2005, claims 1-4 and 9-14 were rejected under 35 U.S.C. 102(b) as being anticipated by Meyer et al. [U.S. Patent No. 5,574,142]. **This rejection is withdrawn** in view of Applicant's Amendment filed December 13, 2005. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to the claims to recite, "A composition comprising an antigen and an immunostimulant oligonucleotide". It is noted that Meyer et al. teach an immunostimulant oligonucleotide in the form of a peptide linker, but do not teach wherein the oligonucleotide comprises an antigen.

In the previous Office Action mailed July 13, 2005, claims 1-3 and 9-14 were rejected under 35 U.S.C. 102(b) as being anticipated by Herman, J. [WO 97/46705]. **This rejection is withdrawn** in view of Applicant's Amendment filed December 13, 2005. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to the claims to recite, "A composition comprising an antigen and an immunostimulant oligonucleotide". It is noted that Herman, J. teach an immunostimulant oligonucleotide in the form of a primer, but do not teach wherein the oligonucleotide comprises an antigen.

In the previous Office Action mailed July 13, 2005, claims 1-3 and 9-14 were rejected under 35 U.S.C. 102(e) as being anticipated by Gonzalgo et al. [U.S. Patent No. 6,251,594]. **This rejection is withdrawn** in view of Applicant's Amendment filed December 13, 2005. Specifically, the Examiner is withdrawing this rejection in view of

Applicant's Amendment to the claims to recite, "A composition comprising an antigen and an immunostimulant oligonucleotide". It is noted that Gonzalgo et al. teach an immunostimulant oligonucleotide in the form of a primer, but do not teach wherein the oligonucleotide comprises an antigen.

Claim Rejections - 35 USC § 112

In the previous Office Action mailed July 13, 2005, claims 1-14 and 19-21 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. **This rejection is moot** against claim 19 in view of Applicant's Amendment filed December 13, 2005 to cancel this claim. **This rejection is withdrawn** against claims 1-14, 20, and 21 in view of Applicant's Amendment filed December 13, 2005. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to the claims to delete the phrase, "in which N_1 and N_2 are not both thymines".

Applicant's Amendment necessitated the new grounds of rejection(s) presented below:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 and 20-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instant claims are drawn to a composition comprising an antigen and an immunostimulant oligonucleotide, the oligonucleotide comprising at least one nucleotide sequence having the formula, 5'-TTN$_1$N$_2$TT-3', wherein T signifies thymine, and N$_1$ and N$_2$ are each independently adenine, thymine, cytosine or guanine, and the nucleotide sequence is selected from the group consisting of:

5'-TTAATT-3; 5'-TTACTT-3; 5'-TTATTT-3; 5'-TTAGTT-3; 5'-TTTATT-3; 5'-TTTCTT-3 5'-TTTGTT-3; 5'-TTCCTT-3; **5'-TTCATTC**; 5'-TTCTTT-3; 5 '-TTGGTT-3; 5'-TTGATT-3; 5'-TTGTTT-3; and 5'-TTGCTT-3 and wherein the oligonucleotide lacks a dinucleotide CG in which the cytosine C is not methylated, and methods of using said composition.

Recitation of the specific nucleotide sequence 5'-TTCATTC (shown above in bold) appears to be new matter.

In the response filed December 13, 2005, Applicants indicate that support for the 14 of the 16 possible sequences comprising 5'-TTN$_1$N$_2$TT-3' can be found at page 11 in the instant specification, for example. Referring to page 11, it is noted that the sequence 5'-TTCATT-3' is recited, but nowhere in the instant specification can the specific sequence of 5'-TTCATTC be found.

Recitation of the specific nucleotide sequence 5'-TTCATTC is new matter. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al. [WO 98/05532].

Claim 1 is drawn to a composition comprising an antigen and an immunostimulant oligonucleotide, the oligonucleotide comprising at least one nucleotide sequence having the formula, 5'-TTN_1N_2TT-3', wherein T signifies thymine, and N_1 and N_2 are each independently adenine, thymine, cytosine or guanine, and the nucleotide sequence is selected from the group consisting of:

5'-TTAATT-3; 5'-TTACTT-3; 5'-TTATTT-3; 5'-TTAGTT-3; 5'-TTTATT-3; 5'-TTTCTT-3 5'-TTTGTT-3; 5'-TTCCTT-3; **5'-TTCATTC**; 5'-TTCTTT-3; 5 '-TTGGTT-3; 5'-TTGATT-3; 5'-TTGTTT-3; and 5'-TTGCTT-3 and wherein the oligonucleotide lacks a dinucleotide CG in which the cytosine C is not methylated. Claims 2, 4, 5, and 9-14 are dependent on claim 1 and include all the limitations of claim 1 with the further limitations wherein the oligonucleotide comprises from 6 to 100 nucleotides, wherein 5'-TTN_1N_2TT-3' is repeated once, wherein 5'-TTN_1N_2TT-3' is repeated twice, and wherein the

composition induces lymphocyte proliferation, specific cytokine secretion, and activation of specific markers.

Wright et al. disclose and claim oligonucleotide compositions comprising SEQ ID NOs: 10, 35, 37, 40, or 41 (see Table 5 and claim 7). It is noted that SEQ ID NOs: 10, 35, 37, 40, or 41 comprise at least one nucleotide sequence having the formula, 5'-TTN_1N_2TT-3', wherein T signifies thymine, and N_1 and N_2 are each independently adenine, thymine, cytosine or guanine, and the nucleotide sequence is selected from the group consisting of 5'-TTGATT-3 (SEQ ID NO:10 or SEQ ID NO:35), 5'-TTGGTT-3 (SEQ ID NO:10 or SEQ ID NO:35), 5'-TTATTT-3 (SEQ ID NO:37 or SEQ ID NO:40), 5'-TTCATT-3 (SEQ ID NO:40), or 5'-TTTGTT-3 (SEQ ID NO:41). It is further noted that specifically SEQ ID NOs: 10, 35, and 40 further comprise wherein 5'-TTN_1N_2TT-3' is repeated once or twice. The oligonucleotides disclosed by Wright et al. meet the structural limitations of the claimed invention and would be expected to function as an immunostimulant oligonucleotide, absent evidence to the contrary.

Wright et al. specifically claim oligonucleotide compositions shown in Table 5 (see claim 7), a ribozyme sequence homologous to claim 7 (see claim 9), and a pharmaceutical composition comprising at least one oligonucleotide of claim 7, and a ribozyme according to claim 9 in admixture (see claim 10). Applicant is reminded that SEQ ID NOs: 10, 35, 37, 40, or 41 are disclosed in Table 5. Given the disclosure of Wright et al., the Examiner is interpreting either one of SEQ ID NOs: 10, 35, 37, 40, or 41 disclosed and claimed by Wright et al. to be the immunostimulant oligonucleotide of Applicant's invention and the ribozyme sequence homologous to either one of SEQ ID

NOs: 10, 35, 37, 40, or 41 disclosed and claimed by Wright et al. to be the antigen of Applicant's invention. Applicant is reminded that Wright et al. disclose and claim a composition comprising both the oligonucleotide and the ribozyme sequence homologous to said oligonucleotide in claim 10.

The burden of establishing whether the prior art composition has the further function of inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting In re Best 195 USPQ 430 as per above. Therefore, it falls to Applicant to determine and provide evidence that the composition disclosed by Wright et al. would or

would not have the additional functional limitation of inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers as claimed.

Therefore, absent evidence to the contrary, claims 1, 2, 4, 5, and 9-14 are anticipated by Wright et al.

Claims 1, 2, and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al. [U.S. Patent No. 5,591,623] as evidenced by National Cancer Institute, Dictionary of Cancer Terms, www.cancer.gov.

The claims are as described above in the 35 U.S.C. 102(b) rejection against claims 1, 2, 4, 5, and 9-14 as being anticipated by Wright et al.

Bennett et al. disclose the oligonucleotide modulation of cell adhesion using antisense oligonucleotides targeted to I-CAM-1. Specifically, Bennett et al. disclose antisense oligonucleotide SEQ ID NO:16, which has the following sequence:

5'-TTGAGAAAGCTTTATTAACT-3' (see Table 1). Bennett et al. disclose that the antisense oligonucleotide was administered with interleukin-1β to cells in culture (see column 15, first column, last paragraph). The antisense oligonucleotide disclosed by Bennett et al. meets the structural limitations of the claimed invention and would be expected to function as an immunostimulant oligonucleotide, absent evidence to the contrary. Further, interleukin-1β is an antigen as it stimulates an immune response in animals. For further information, see attached National Cancer Institute, Dictionary of Cancer Terms, www.cancer.gov., definition of interleukin-1.

The burden of establishing whether the prior art composition has the further function of inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting In re Best 195 USPQ 430 0as per above. Therefore, it falls to Applicant to determine and provide evidence that the composition disclosed by Bennett et al. would or would not have the additional functional limitation of inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers as claimed.

Therefore, absent evidence to the contrary, claims 1, 2, and 9-14 are anticipated by Bennett et al.

Claims 1, 2, 9-14, 20-22, 29, 36, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Schlingensiepen et al. [WO 99/63975]

Claims 1, 2, and 9-14 are as described above in the 35 U.S.C. 102(b) rejection against claims 1, 2, 4, 5, and 9-14 as being anticipated by Wright et al. Claims 20-22, 29, 36, and 37 are drawn to a method of stimulating or enhancing an immune response in a human comprising administering a composition comprising an antigen and an immunostimulant oligonucleotide, the oligonucleotide comprising at least one nucleotide sequence having the formula, 5'-TTN$_1$N$_2$TT-3', wherein T signifies thymine, and N$_1$ and N$_2$ are each independently adenine, thymine, cytosine or guanine, and the nucleotide sequence is selected from the group consisting of:

5'-TTAATT-3; 5'-TTACTT-3; 5'-TTATTT-3; 5'-TTAGTT-3; 5'-TTTATT-3; 5'-TTTCTT-3 5'-TTTGTT-3; 5'-TTCCTT-3; **5'-TTCATTC**; 5'-TTCTTT-3; 5 '-TTGGTT-3; 5'-TTGATT-3; 5'-TTGTTT-3; and 5'-TTGCTT-3 and wherein the oligonucleotide lacks a dinucleotide CG in which the cytosine C is not methylated

Schlingensiepen et al. disclose and claim a composition comprising a combination of at least one inhibitor of the effect of a substance negatively effecting an immune response selected form the group consisting of TGF-β and VEGF, and their receptors, and at least one stimulator positively effecting an immune response (see Abstract and claim 1). More specifically, Schlingensiepen et al. disclose oligonucleotides 137 (effective against VEGF), 140 (effective against VEGF), 201 (effective against TGF-β), and 202 (effective against TGF-β). It is noted that oligonucleotides 137, 140, 201, and 202 comprise at least one nucleotide sequence

having the formula, 5'-TTN$_1$N$_2$TT-3', wherein T signifies thymine, and N$_1$ and N$_2$ are each independently adenine, thymine, cytosine or guanine, and the nucleotide sequence is selected from the group consisting of 5'-TTTGTT-3 (oligonucleotide 137), 5'-TTCTTT-3 (oligonucleotides 140 and 201), and 5'-TTTCTT-3 (oligonucleotide 202). Given the disclosure of Schlingensiepen et al., the Examiner is interpreting either one of oligonucleotides 137, 140, 201, and 202 disclosed and claimed by Schlingensiepen et al. to be the immunostimulant of Applicant's invention and either one of oligonucleotides 137, 140, 201, and 202 disclosed and claimed by Schlingensiepen et al. to be the antigen of Applicant's invention. Applicant is reminded that Schlingensiepen et al. disclose and claim a composition comprising a combination of at least one inhibitor of the effect of a substance negatively effecting an immune response selected form the group consisting of TGF-β and VEGF, and their receptors, and at least one stimulator positively effecting an immune response in claim 1.

Schlingensiepen et al. also claim a method of administering the previously mentioned composition to a human patient (see claim 12). It is noted that Schlingensiepen et al. are silent regarding whether their method of administering a composition comprising a combination of at least one inhibitor of the effect of a substance negatively effecting an immune response selected form the group consisting of TGF-β and VEGF, and their receptors, and at least one stimulator positively effecting an immune response will stimulate or enhance an immune response in a human. However, since the method recited by Schlingensiepen et al. recites the same method step as instantly claimed, it is the Examiner's position that the method of administering

the previously mentioned composition to a human patient disclosed by Schlingensiepen et al. will stimulate or enhance an immune response in a human, absent evidence to the contrary.

Furthermore, the burden of establishing whether the prior art composition has the further function of stimulating an immune response in a human, or inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting In re Best 195 USPQ 430 0as per above. Therefore, it falls to Applicant to determine and provide evidence that the composition disclosed by Schlingensiepen et al. would or would not have the additional functional limitation of stimulating an immune response in a human, or

inducing lymphocyte proliferation, specific cytokine secretion, and activation of specific markers as claimed.

Therefore, absent evidence to the contrary, claims 1, 2, 9-14, 20-22, 29, 36, and 37 are anticipated by Schlingensiepen et al.

Conclusion

Claims 8, 28, 35, and 43 are objected to as being dependent upon a rejected base claims, but would be allowable if rewritten to remove nonelected subject matter and rewritten in independent form to include all of the limitations of the base claim and any intervening claims. Claims 8, 28, 35, and 43 are considered to be free of the prior art since the prior art does not teach or fairly suggest a composition comprising an antigen and an immunostimulant oligonucleotide, the oligonucleotide comprising at least one nucleotide sequence having the formula, 5'-TTN_1N_2TT-3', wherein T signifies thymine, and N_1 and N_2 are each independently adenine, thymine, cytosine or guanine, wherein the composition comprises the sequence of SEQ ID NO:17 and methods of using SEQ ID NO:17 to stimulate or enhance an immune response in a human.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

tcg
December 11, 2006

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER